Supreme Court, U.S.
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No. 02-869

In The
Supreme Court of the United States

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Petitioner,

v.

RHONDA M. MEDOWS, Secretary, Agency for Health Care Administration of the State of Florida, and BOB SHARPE, Deputy Secretary of Medicaid, Agency for Health Care Administration of the State of Florida,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Eleventh Circuit

OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

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COUNTERSTATEMENT OF QUESTION PRESENTED

Whether the ability of a State to subject a prescription drug covered by its Medicaid program to a prior authorization requirement under Section 1927(d)(1)(A) of the Social Security Act is constrained by the rules set forth in Section 1927(d)(4), which govern when a state may exclude a drug from coverage on a restrictive formulary?

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INTRODUCTION

This case arises out of an effort by one of the nation's largest business associations to enforce its own unique interpretation of federal law against the State of Florida, so that it may prevent the State from seeking to reduce the amount of money it spends on prescription drugs purchased through its Medicaid program. Specifically, the Pharmaceutical Research and Manufacturers of America ("PhRMA") claims that federal law prohibits Florida from subjecting certain drugs covered under its Medicaid program to a prior authorization requirement in order to encourage the manufacturers to lower the prices they charge Medicaid for those drugs.

The Eleventh Circuit, affirming the District Court, rejected this claim because the plain text of the Medicaid statute authorizes Florida to subject "any covered outpatient drug" to a prior authorization requirement. Similarly, the agency that is statutorily charged with enforcing the Medicaid statute, the Center for Medicaid and Medicare Services ("CMS"), has concluded that the Medicaid statute in no way prohibits Florida from using its prior authorization power to negotiate discounts on the prescription drugs it purchases for Medicaid patients. In addition, the Solicitor General has submitted a brief to this Court confirming the view of the United States that PhRMA's argument is "without merit." No Court has ever held otherwise, and, indeed, PhRMA cannot point to *any authority* to support its assertion that states are prohibited from using prior authorization to negotiate prescription drug rebates for their Medicaid programs.

There is therefore no reason to grant PhRMA's Petition. There is no conflict between the Eleventh Circuit's decision in this case and the decision of any other Court. As confirmed by the views of CMS and the Solicitor General, the issue PhRMA presents is not of such pressing "national importance" as to justify this Court's taking the

case before any such potential conflict emerges, and before other circuit courts have a chance to address it. Recognizing this, PhRMA seizes upon this Court's decision to hear the case of *PhRMA v. Concannon* (No. 01-188). But in that case, PhRMA challenged Maine's attempt to use its prior authorization power to extract rebates on prescription drugs purchased by *non*-Medicaid patients. PhRMA's theory in that case, supported by the Solicitor General and CMS, is that a state is not free to use its powers under the Medicaid statute to extract rebates from pharmaceutical companies for non-Medicaid purposes. Here, Florida has done no such thing. Its program seeks only to save money for Medicaid, not for anything else. For that reason, this case and *Concannon* are fundamentally different.

Finally, the Petition should be denied because the only way PhRMA can enjoin a state from implementing a program that it claims is in conflict with a federal law is by showing that Congress intended that federal law to confer an enforceable right on PhRMA's members. This it cannot do. It is quite clear that in enacting the provision of the Medicaid statute invoked in this case, Congress did not intend to confer enforceable rights on pharmaceutical companies. Thus, this Court should not entertain PhRMA's attempt to usurp CMS's statutorily assigned function of interpreting and enforcing the Medicaid laws.

STATEMENT OF THE CASE

The issue presented in this case is whether the federal Medicaid statute forbids Florida to divide the prescription drugs it covers under Medicaid into two categories: those that are "preferred," which Medicaid pays for automatically; and those that are not preferred, which Medicaid pays for only after the prescribing physician has first contacted a pharmacist designated by Florida's Agency for

Health Care Administration ("AHCA") in order to receive "prior authorization." An understanding of this dispute requires only a brief description of the relevant provisions in the Medicaid statute and of the Florida program that PhRMA challenges.

I. The Medicaid Statute: The Difference Between Prior Authorization Restrictions And Exclusion Of A Drug From A Restrictive Formulary

The federal Medicaid statute was enacted in 1965 as title XIX of the Social Security Act ("SSA"), and is codified at 42 U.S.C. § 1396 et seq. ("the Medicaid statute"). The Medicaid statute does not require states to offer prescription drug benefits to Medicaid patients. 42 U.S.C. § 1396d(a)(12). Nevertheless, most (but not all) states offer at least some level of drug coverage, though only slightly more than half have chosen to offer this coverage to the broadest possible class of Medicaid recipients.

The financial burden on states of Medicaid prescription drug coverage is enormous, and skyrocketing at an alarming rate. In Florida, the state's appropriations for Medicaid prescribed drug spending rose from $1.65 billion in fiscal year 2001/02 to $1.88 billion in fiscal year 2002/03, an increase of almost 14% for only a single year.[1] This precipitous increase is even more dramatic when compared to the $1.24 billion appropriation for fiscal year 1999/00, an increase of over 50% in just a three-year

[1] State of Florida, Agency for Health Care Administration's September 30, 2002 Quarterly Report on Medicaid Prescribed Drug Spending Control Initiatives, *available at* http://www.fdhc.state.fl.us/Medicaid/deputy_secretary/recent_presentations/mpdscpi_qtrly_report_093002.pdf.

period.[2] These increases reflect higher costs for prescription drugs: over the past decade, the average cost per prescription has grown from $24.91 to $72.51.[3] Florida's experience is typical, which is why states throughout the country have been faced with the unenviable choice of eliminating prescription drug coverage, or finding some way to negotiate lower drug costs.

Prior to 1990, states could limit their exposure to the high costs of prescription drugs in one of two ways: they could "exclude coverage" of any prescription drugs that they did not wish to cover; or, they could choose to cover certain drugs only if the prescribing physician first requested prior authorization. Indeed, "[b]efore 1990, states had routinely required prior authorization for prescription or dispensing of drugs in order to control Medicaid costs."[4]

In an effort to help control increasing drug costs under Medicaid, Congress enacted SSA § 1927 in 1990. This legislation preserved the traditional ability of states to use prior authorization restrictions to control drug costs, but replaced the state practice of excluding drugs from being eligible for Medicaid coverage altogether with a federal system for determining which drugs should be covered under Medicaid. Congress required all drug manufacturers who wished to have their drugs covered under Medicaid to offer at least a minimal discount, equal to the

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[2] *Id.*

[3] 2001 Annual Report – Medicaid Prescribed Drug Spending Control Program at 3, *available at* http://www.fdhc.state.fl.us/Medicaid/Prescribed_Drug/presentations.shtml.

[4] Brief of the Solicitor General ("SG amicus") at 14, *PhRMA v. Concannon,* No. 01-188 (U.S. filed July 31, 2001) (citing legislative history).

larger of either 15.1 percent of the manufacturer's average price for that drug, or the lowest price charged by the manufacturer for that drug. 42 U.S.C. § 1396r-8(c)(1). This discount is paid pursuant to an agreement entered into between the drug company and the Secretary of the Department of Health and Human Services ("the Secretary"), and is known informally as the "federal rebate." As of 1990, the law provided that if a manufacturer paid the federal rebate, then a state was no longer free to exclude that manufacturer's drugs from Medicaid coverage altogether. 42 U.S.C. § 1396a(a)(54). Assuming they satisfy certain federal law requirements, prescription drugs produced by manufacturers who have entered into federal rebates are "covered outpatient drugs."

Congress went out of its way, however, to ensure that states could continue their practice of using prior authorization restrictions to control costs. Before 1990, there had been no provision of law expressly permitting states to use this power. *See* 136 CONG. REC. S15,629, S15,658 (Oct. 18, 1990) (noting absence of any "federal laws or regulations governing prior authorization programs"). In order to make clear that states could continue exercising this traditional power, Congress enacted a provision that Florida maintains is of dispositive significance to this case, even though PhRMA failed to mention it in its Statement of the Case. Under subsection (d)(1)(A) of SSA § 1927,[5] states may restrict coverage by subjecting "any covered outpatient drug" that is covered under Medicaid to a prior authorization restriction. 42 U.S.C. § 1396r-8(d)(1)(A). The only limitations that Congress placed on this prior authorization power require the state to respond to requests

[5] Throughout this brief, we use "subsection" to refer to subsections of SSA § 1927 (as codified at 42 U.S.C. § 1396r-8).

for prior authorization (within 24 hours) and to provide emergency dispensations of such drugs (a 72-hour supply). 42 U.S.C. § 1396r-8(d)(5) ("the 24/72 requirements"). Florida complies fully with these requirements, FLA. STAT. § 409.912(37)(a)(1)(a), (b), and PhRMA does not allege otherwise.

In enacting subsection (d)(1)(A) in 1990, Congress noted that it was providing states with "the option of imposing prior authorization requirements with respect to covered prescription drugs in order to safeguard against unnecessary utilization and assure that payments are consistent with efficiency, economy, and quality of care." H.R. REP. NO. 101-881, pt. 1, at 98 (1990). Accordingly, after the 1990 enactment of SSA § 1927, while states could not exclude from Medicaid coverage altogether any drug produced by a manufacturer paying a federal rebate, they were free to subject any such drug to a prior authorization restriction in an effort to control their exposure to drug costs, just as they traditionally had in the past.

Finally, as an additional measure to allow State Medicaid programs to reduce prescription drug costs, Congress also authorized states to enter into rebate agreements directly with the drug manufacturers, subject to the approval of the Secretary. 42 U.S.C. § 1396r-8(a)(1). These state rebate agreements can be either supplemental to, or in lieu of, the federal rebate agreement, but in no event may they result in a total rebate to the Medicaid program that is less of a price savings than the standard federal rebate. 42 U.S.C. § 1396r-8(a)(4).

The forgoing is undisputed in this case, and the parties agree that the enactment of SSA § 1927 in 1990 codified the states' pre-existing ability to impose a prior authorization requirement on "*any* covered outpatient drug," subject only to its obligation to comply with the 24/72 requirements. The dispute here centers instead upon

the significance of a subsequent amendment to SSA § 1927 that authorized states to "exclude[ ] coverage of [a] drug from its formulary." 42 U.S.C. § 1396r-8(d)(1)(B)(iv). In 1993, Congress enacted subsection (d)(4), which permits a state to exclude a drug from coverage if it first appoints a properly constituted committee of physicians and therapeutic pharmacists ("P&T Committee") that then determines that the drug "does not have a significant, clinically meaningful therapeutic advantage" over alternative medications in its therapeutic class, and provides a written explanation for its exclusion decision. 42 U.S.C. § 1396r-8(d)(4). When a state has excluded coverage of a drug from its formulary, it must still "permit[ ] coverage of [the] drug . . . pursuant to a prior authorization program that is consistent with [the 24/72 requirements of] paragraph (5)." 42 U.S.C. § 1396r-8(d)(4)(D).

PhRMA appears to agree that subsection (d)(4) was intended to grant states additional power that they did not have after the 1990 enactment of SSA § 1927. Pet. at 5 ("Congress in 1993 restored the states' ability to establish Medicaid formularies").

II. Florida's Preferred Drug List

In May 2001, Florida amended certain provisions of its Medicaid laws governing the coverage of prescription drugs. Chapter 2001-104 of the ~~2001~~ Florida Laws, ("2001 amendments") amending, *inter alia*, FLA. STAT. §§ 409.91195, 409.912. These 2001 amendments created a P&T Committee, and directed this P&T Committee to work with AHCA to develop a preferred drug list ("PDL"). Beginning in August of 2001, the P&T Committee has met on a monthly basis to consider which drugs should be included on the PDL and which should not.

The purpose and effect of Florida's PDL is to identify drugs that are subject to prior authorization. If a drug is

on the PDL, Medicaid will pay for the drug automatically without the prescribing physician contacting anyone. If a drug is not on the PDL, it is nonetheless still covered under Florida's Medicaid program, but the prescribing physician must contact an AHCA pharmacist before Medicaid will pay for it. The AHCA pharmacist has no discretion to deny prior authorization; thus, the prescribing physician is *guaranteed* to receive authorization.[6] The only purpose served by requiring the physician to request authorization from an AHCA pharmacist is to inform the physician that AHCA recommends alternative, normally less expensive drugs that are in the same therapeutic class, or are therapeutically equivalent.[7] The 2001 amendments also authorized Florida to negotiate with manufacturers for state rebates that supplement the

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[6] For this reason, even calling Florida's PDL a prior authorization program overstates the extent to which the availability of non-PDL drugs is in any way restricted. While the phrase "prior authorization" suggests the theoretical possibility of *not* being authorized, the district court correctly concluded that "strictly speaking, the Florida program is not even an 'authorization' program. It is only a program by which the State informs physicians of preferred, less expensive drugs." App. 56.

[7] This Court should not credit any suggestion by PhRMA that Florida's prior authorization in any way threatens to harm Medicaid patients. *See, e.g.,* Pet. at 9 n.5. While prior authorization may cause a change in the prescription habits of physicians, there is no reason to believe those changes are harmful to patients. To the contrary, since the physician retains ultimate clinical control, any change in a prescription is one made by the physician. Thus, for there to be harm to the patient, the physician would have to compromise his professional obligations merely to avoid a 3-minute phone call to obtain prior authorization. Supplemental Affidavit of George Kitchens at ¶ 5 (Doc. 49, Record on Appeal, *PhRMA v. Medows*, No. 4:01-CV-356 (N.D. Fla. 2001)). Moreover, the study to which PhRMA cites to show that prescription habits have changed, *see* Pet. at 9 n.5 (citing study by Mary Kay Owens, et al.), is not part of the record in this case, and has been vigorously contested by Florida in another lawsuit.

federal rebate ("supplemental rebates"). In order to be considered for placement on the PDL, a drug must generally have either a supplemental rebate of 10 percent, or a total (federal and supplemental) rebate of 25 percent.

A drug is not guaranteed placement on the PDL by simply paying the supplemental rebate. The key considerations in determining which drugs are placed on the PDL are clinical efficacy, safety, and cost. Thus, any drug that is at least as safe and effective as other drugs in its therapeutic class can be placed on the PDL irrespective of whether or not its manufacturer has agreed to pay a supplemental rebate to Florida. As of 2001, approximately 78 percent of the National Drug Codes ("NDCs") for brand-name drugs on the PDL refer to drugs for which the manufacturers do not pay a supplemental rebate.[8] On the other hand, where competing drugs within a therapeutic class are capable of providing essentially identical clinical benefits, AHCA generally places the less expensive of these drugs on the PDL. For these clinically equivalent drugs, the PDL will typically include generic versions (so long as the P&T Committee finds that they are both clinically efficacious and safe), as well as any brand-name drugs for which the manufacturer has agreed to pay a supplemental rebate.

As of October 2001, Florida's PDL contained approximately 70.3 percent of all the NDCs that referred to drugs produced by manufacturers who had entered into a federal rebate.[9]

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[8] Supplemental Affidavit of George Kitchens at ¶ 3 (Doc. 49).

[9] *Id.* at ¶ 2. While the percentage of federally-rebated drugs on the PDL may be somewhat different if calculated by using a definition of "drugs" other than NDCs, even PhRMA agrees that close to half of the federally-rebated drugs appear on the PDL, Pet. at 7; Complaint ¶ 36 (alleging that 821 out of the 1,827 prescription drugs covered by federal

(Continued on following page)

REASONS FOR DENYING THE PETITION

PhRMA's Complaint in this case, and the arguments it offers for granting its Petition, rest upon a single legal theory: that "SSA § 1927(d)(4) limits a state's ability to impose broad restrictions on Medicaid patients' access to a manufacturer's drugs, unless the manufacturer has agreed to pay the state a greater rebate than the rebate specified in the federal statute." Pet. at 13. PhRMA's "formulary argument," at least as articulated thus far, asserts that *whenever* a state imposes "broad restrictions on Medicaid patients' access to a manufacturer's drugs," it must satisfy the requirements of subsection (d)(4) for excluding coverage of a drug on a formulary.

As explained in Section III below, both lower courts correctly rejected this argument, as directly contradicting the plain text of subsection (d)(1)(A), which permits a state to subject "any covered outpatient drug" to a prior authorization requirement. Likewise, there is no substance to any of the reasons PhRMA offers in support of its Petition: The United States, far from inviting this Court to consider the formulary argument in its amicus brief in the *Concannon* case, actually told this Court that the argument is "without merit." And PhRMA's formulary argument is hardly one of "national importance" that must be resolved before any other states consider implementing programs such as Florida's. If it were, presumably CMS would not have advised all State Medicaid Directors that PhRMA's formulary argument is wrong, and in no way limits their ability to use prior authorization requirements to negotiate lower drug costs. Finally, there is no reason to hold this Petition pending the disposition of *Concannon*: that case raises the very different question of whether a state may leverage its

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rebates are on the PDL), and a great many of these do so without their manufacturer having to pay a supplemental rebate.

prior authorization power to extract drug rebates for the benefit of *non*-Medicaid patients. Florida has not done this, and the disposition of *Concannon,* therefore, will not affect the Florida program.

More fundamentally, as demonstrated in Section II(A) below, PhRMA cannot properly bring any of the statutory claims it has launched against the various states that have sought to lower their Medicaid drug costs through use of prior authorization requirements, for PhRMA has invoked provisions of the Medicaid statute that do not confer enforceable rights on pharmaceutical companies. Thus, on the strength of nothing more than the financial interests of some of its members, PhRMA is simply trying to usurp CMS's statutorily assigned function to both interpret and enforce the provisions of the Medicaid statute. This it cannot do, least of all where its substantive claim is so transparently weak.

I. The United States Has Not Invited This Court To Consider The Question Presented In This Case.

Citing to the Solicitor General's amicus brief in *Concannon*, PhRMA asserts that "the United States has invited the Court to address the issue presented by this case: whether the federal Medicaid statute's formulary provision, SSA § 1927(d)(4), limits a state's ability to use prior authorization to compel manufacturers to pay supplemental rebates on drugs prescribed to Medicaid recipients." Pet. at 14. In truth, the United States summarily dismissed the issue as meritless, arguing that "the drug formulary provisions . . . furnish no basis for limiting a State's ability to establish a prior authorization program in order to obtain additional drug rebates for Medicaid recipients." SG amicus at 18.

Indeed, the United States' *Concannon* brief could not be clearer, or more forceful, in its rejection of the position

PhRMA advances in this case. First, it recounts that "Congress in 1990 passed the prior authorization provisions of 42 U.S.C. §§ 1396r-8(d)(1) and (5) to preserve the States' historic discretion to subject drugs to prior approval to contain Medicaid costs." SG amicus at 18. It then explains that "[t]he formulary provisions of Section 1396r-8(d)(4), which Congress added to the drug rebate provisions in 1993, gave States *additional* authority to exclude covered drugs, without modifying (much less detracting from) the States' well-established power to institute prior authorization programs." *Id.* (emphasis in original). And, as the United States further noted, Congress was unambiguous that these formulary rules in no way constrained the preexisting power of states to impose prior authorization restrictions, since it "expressly provided in the last sentence [of (d)(4)] that 'a prior authorization program established by a State under [42 U.S.C. § 1396r-8(d)(5)] *is not a formulary* subject to the requirements of this paragraph.'" *Id.* (second alteration in original). The United States' absolute and unqualified rejection of PhRMA's formulary argument as "without merit," *id.* at 17, hardly constitutes an "invitation" to grant *certiorari*.

As PhRMA acknowledges, the question PhRMA presents in this case was "neither raised by the parties in [*Concannon*] nor decided by either the district court or the court of appeals." Pet. at 16. We therefore agree with PhRMA that *Concannon* "does not present an appropriate occasion to consider" whether the formulary rules of Section 1927(d)(4) somehow limit a state's prior authorization power set forth in Section 1927(d)(1)(A). *Id.* The fact that PhRMA failed to raise the issue in *Concannon* hardly makes it worthy of *certiorari* in this case. To the contrary, PhRMA's failure to assert the formulary argument in *Concannon* suggests only that PhRMA had not yet invented the argument when it sued Maine. Not until after the First Circuit had rejected PhRMA's other statutory and constitutional attacks in *Concannon* (on May 16,

2001) did PhRMA first assert its formulary argument in its Complaint against Florida (filed August 7, 2001). Since then, the argument has been rejected resoundingly by the courts that have considered it. That the United States has now dispatched summarily the argument in its brief in *Concannon* only confirms that it does not warrant a grant of *certiorari* here.

II. PhRMA's Formulary Argument Does Not Present "An Important Question Of Federal Law."

Asserting that "states at various stages of adopting provisions similar to Florida's will look to this case to determine the legality of those programs," PhRMA argues "[i]t is important that this Court clarify whether states may enforce supplemental Medicaid rebate requests by using their prior authorization powers in a way that evades the requirements of SSA § 1927(d)(4)." That PhRMA's formulary argument is completely lacking in merit (see Section III, below) is itself reason enough to ignore this claim. But this claim is singularly unpersuasive for three additional reasons that are even more fundamental.

First, the formulary provisions in the Medicaid statute do not confer an enforceable right on pharmaceutical companies, and PhRMA therefore does not even have a right to bring its formulary argument before this or any other court. Second, the agency statutorily charged with enforcing the Medicaid statute – CMS – has unambiguously *rejected* PhRMA's formulary argument. Finally, the fact that some other states have initiated programs similar to Florida's counsels *against* this Court's review at this time. PhRMA is litigating against all of these states, and until at least one court finds any merit in its formulary argument, this Court ought to follow its normal

practice of allowing the issue to be ventilated among the lower courts.

A. PhRMA Has No Right To Enforce The Formulary Provision Of The Medicaid Statute.

PhRMA's Complaint in this case invokes both the Supremacy Clause and 42 U.S.C. § 1983 as its basis for seeking to enforce the Medicaid statute against Florida. This Court has made clear that neither the Supremacy Clause nor Section 1983 confers any substantive rights. *See generally Golden State Transit Corp. v. Los Angeles*, 493 U.S. 103, 107 (1989) (Supremacy Clause "is not a source of federal rights") (quotation omitted); *Chapman v. Houston Welfare Rights Org.*, 441 U.S. 600, 617 (1979) (Section 1983 "did not provide for any substantive rights"). Thus, the only way a litigant may enjoin a state from acting contrary to federal law is by showing that the federal law in question confers a substantive right on that litigant. *See generally Blessing v. Freestone*, 520 U.S. 329, 333 (1997); *Suter v. Artist M.*, 503 U.S. 347, 350 (1992).

Here, PhRMA claims that Florida's PDL violates the formulary requirements of SSA § 1927(d)(4). But this provision does not confer an enforceable right on pharmaceutical companies. First, Section 1927 does not impose any unconditional obligations on states; rather, it merely sets forth the requirements that states must satisfy in order to receive financial assistance from the federal government. *See* 42 U.S.C. § 1396r-8(a)(1). In this context, where Congress has exercised its power under the Spending Clause to condition the federal government's financial assistance to states based upon the states' fulfilling certain preconditions, this Court has been very reluctant to interpret the statute as conferring enforceable rights on private persons. *See generally Gonzaga Univ. v. Doe*, 122 S. Ct. 2268, 2274 (2002) (holding that Court's "more recent decisions . . . have rejected attempts to infer enforceable

rights from Spending Clause statutes"); *Suter v. Artist M.*, 503 U.S. at 350.

Moreover, even PhRMA appears to admit that the only private parties with enforceable rights under the formulary requirements are Medicaid patients, not pharmaceutical companies. PhRMA asserts that the reason Congress imposed subsection (d)(4)'s limitations on a state's ability to exclude drugs from a formulary was "in order to ensure that Medicaid *patients* would not be denied ready access to the most advantageous drugs based on non-clinical considerations, such as cost." Pet. at 4 (emphasis added). Thus, PhRMA admits that the very rule it claims Florida has violated was enacted not to protect pharmaceutical companies, but rather to protect Medicaid *patients*. Since a statute can confer an enforceable right on a particular class of plaintiffs only if it has an "'unmistakable focus on [that] benefited class,'" *see Gonzaga Univ.*, 122 S. Ct. at 2277 (citation omitted), a provision that in no way seeks to benefit drug companies cannot possibly confer an enforceable right on PhRMA.

PhRMA has no right of action to enforce the formulary provision. Congress instead gave that job to CMS, and, as noted, CMS has specifically refuted the interpretation of law that PhRMA advances. While Florida raised this point before the district court,[10] the district court did not address it. And the issue was neither raised in nor addressed by the court of appeals. Whether or not Florida has waived this argument, the fact that PhRMA is asking this Court to enforce a right under the Medicaid statute that Congress clearly did not intend to create *at least* counsels against granting *certiorari*.

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[10] Defendants' Motion and Memorandum to Dismiss, or in the Alternative, for Summary Judgment (Doc. 21) at 13-15.

B. This Court Should Defer To CMS's Rejection Of PhRMA's Formulary Argument.

Consistent with the views expressed in the Solicitor General's *Concannon* brief, CMS, the agency that is statutorily charged with administering and enforcing the Medicaid statute, has also specifically rejected PhRMA's formulary argument. On September 18, 2001, CMS published its view to all State Medicaid Directors that "[s]tates may subject covered outpatient prescription drugs to prior authorization as a means of encouraging drug manufacturers to enter into separate or supplemental rebate agreements for covered drugs purchased by Medicaid recipients." Sept. 18, 2002 CMS letter ("CMS letter") at 2.

In its Petition, PhRMA acknowledges that CMS endorsed the states' use of prior authorization requirements to obtain supplemental drug rebates (Pet. at 18 n.8); however, PhRMA fails to mention that CMS did more than that, and formally notified all State Medicaid Directors that "[a] prior authorization program does not need to comply with the requirements for restrictive formularies." CMS letter at 2. CMS explained that "[t]he formulary provisions of section 1927(d)(4) were added to the drug rebate provisions in 1993 to give states *additional* authority to implement restrictive formularies," *id.* (emphasis added), thus negating the notion that these provisions were intended to limit the preexisting power of states to subject "any covered outpatient drug" to prior authorization. CMS also rejected PhRMA's argument that the prior authorization power is somehow limited to "concerns related to drug use, monitoring, waste, fraud or abuse"; given that those specific concerns are all addressed through other provisions, "a prior authorization program need not be limited to those concerns." *Id.* Finally, CMS, like the Solicitor General, pointed out that Congress itself specifically rejected PhRMA's argument in the last sentence of subsection (d)(4), where it "expressly stat[ed] that '[a] prior authorization program established by a State

under [Section 1927(d)(5)] is not a formulary subject to the requirements of this paragraph.'" *Id.* (quoting SSA 1927(d)(4)).

PhRMA argues that CMS's opinion letter is not entitled to deference, but the only support it offers for that claim is a decision of this Court confirming that "interpretations contained in formats such as opinion letters are 'entitled to respect' under our decision in *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944)," at least "to the extent that those interpretations have the 'power to persuade.'" *Christensen v. Harris County*, 529 U.S. 576, 587 (2000) (citation omitted); *see also Wisconsin Dep't of Health & Family Servs. v. Blumer*, 534 U.S. 473, 497 (2002) (granting "respectful consideration" to and adopting position consistent with Secretary's interpretation in proposed rule and HCFA regional state letter).

Here, the rejection of PhRMA's formulary argument set forth in CMS's opinion letter (and in the Solicitor General's *Concannon* brief) plainly has the "power to persuade." It relies directly upon the plain text of subsection (d)(1)(A), which provides a state with the power to subject "any covered outpatient drug" to prior authorization, and concludes that the limitations set forth in subsection (d)(4) – which never even mention (d)(1)(A) let alone seek to limit or repeal it – cannot possibly be read to constrain that power. As explained below in Section III, this interpretation of the law not only has the "power to persuade," it is plainly the only correct reading of the Medicaid statute.

C. This Court Ought To Follow Its Normal Practice Of Allowing This Issue To Develop Among The Lower Courts.

Pointing to the fact that Michigan, Vermont, and New Mexico have initiated drug rebate programs similar to Florida's, PhRMA asks this Court to review the Eleventh Circuit's decision before any other court of appeals has had

a chance to consider the issue. This is an exceedingly odd argument to advance for granting *certiorari*. Normally, when "an important federal question" is likely to be addressed by numerous courts of appeals, this Court will not review the first appellate decision to reach the issue, but rather will wait until a conflict develops among the circuits or the issue is otherwise more fully developed. *See generally* SUP. CT. R. 10(a). Only two courts have thus far ruled upon PhRMA's formulary argument, and both have rejected it. The issue is virtually certain to receive consideration by other circuits in due course: Indeed, PhRMA is currently asking the District Court for the District of Columbia to enjoin Michigan's program, based largely upon this same formulary argument.[11]

Nor has PhRMA offered any reason why it is of "national importance" for this Court to intercede at this stage and preempt the ordinary process of allowing the circuit courts to assess the merits of this issue. To the contrary, if this argument really was of such profound significance, PhRMA surely would have raised it when it sought to enjoin Maine's drug rebate initiative. It would appear to have the same application to that case as it does to this one, yet PhRMA neglected to surface it. Having failed to raise this argument against the first State it sued, PhRMA cannot now be heard to argue that the issue is of such pressing "national importance" that this Court's immediate review is warranted.

III. The Eleventh Circuit Was Correct To Reject PhRMA's Formulary Argument.

PhRMA asserts that Florida's imposition of a prior authorization requirement on the non-PDL drugs "amounts

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[11] *See PhRMA v. Thompson*, No. 02-CV-1306 (JB) (D.D.C. filed June 28, 2002); *see also PhRMA v. Thompson*, 251 F.3d 219 (D.C. Cir. 2001) (invalidating earlier Vermont prescription drug program).

to the creation of a state Medicaid formulary; and if a state creates a Medicaid formulary, it may not exclude drugs from routine coverage without making the clinical determinations required by SSA § 1927(d)(4)(C)." Pet. at 13-14. The Eleventh Circuit rejected this argument. At the outset, it correctly observed that because Medicaid is a cooperative state-federal program, this Court has held that "'the case for federal pre-emption becomes a less persuasive one.'" App. 18 (quoting *New York State Dep't of Soc. Servs. v. Dublino*, 413 U.S. 405, 421 (1973)). It then went on to hold that PhRMA's claim in this case depends upon an erroneous interpretation of both federal law and state law. PhRMA's interpretation of the Federal Medicaid statute is wrong because there is a fundamental distinction under federal law between subjecting a drug to a prior authorization condition and excluding it from coverage altogether by excluding it from a restrictive formulary. And PhRMA's interpretation of state law was wrong because it was reasonable for AHCA to implement Florida's 2001 amendments by imposing prior authorization conditions, rather than by requiring drugs to be excluded from coverage on a formulary. PhRMA has presented no reason to question either of these holdings.

A. The Eleventh Circuit Correctly Ruled That Federal Law Distinguishes Between Subjecting A Drug To Prior Authorization And Excluding That Drug From Coverage On A Formulary.

By arguing that Florida's prior authorization requirement for non-PDL drugs "amounts to" an exclusion of those drugs from a restrictive Medicaid formulary, PhRMA has taken the position that there is no difference between "excluding a drug from coverage" and subjecting a covered drug to a prior authorization restriction. PhRMA argues that the Eleventh Circuit "erroneously concluded that Florida had not created a formulary based on the court's mistaken view that a formulary 'has the effect of *excluding*

coverage of, or payment for, certain Medicaid-eligible drugs,' (App. 9), whereas the Florida program 'merely *conditions* coverage for non-preferred drugs on whether the prescribing physician has followed the prior authorization procedure.' (App. 27-28)." Pet. at 20. PhRMA says "[t]hat distinction [between exclusions from coverage altogether and a prior authorization restriction] cannot be reconciled with the language of the Medicaid statute." Pet. at 21.

PhRMA is wrong: the plain text of the Medicaid statute creates this very distinction in the clearest possible terms. In subsection (d)(1), the statute sets forth two separate sets of rules governing two separate ways of restricting or excluding Medicaid coverage of prescription drugs. First, subsection (d)(1)(A) provides:

> A state may subject to prior authorization *any* covered outpatient drug. Any such prior authorization program shall comply with the requirements of paragraph (5).

(Emphasis added).

Paragraph (5) only confirms that states have the ability to subject "any covered outpatient drug" to prior authorization:

> A State plan under this title may require, *as a condition of coverage or payment for a covered outpatient drug* . . . the *approval* of the drug *before* its dispensing for any medically accepted indication (as defined in subsection (k)(6)) only if the system providing for such approval –
>
> (A) provides response by telephone or other telecommunication device within 24 hours of a request for prior authorization; and
>
> (B) . . . provides for the dispensing of at least 72-hour supply of a covered outpatient prescription drug in an emergency situation (as defined by the Secretary).

(Emphases added).

The plain text of subsections (d)(1)(A) and (d)(5) are open to no possible interpretation other than that a state has the right to subject *any* covered outpatient drug to prior authorization so long as the state complies with the 24/72 requirements. Since Florida has indisputably complied with the 24/72 requirements, it is statutorily authorized to subject all non-PDL drugs to a prior authorization restriction.

Subsection (d)(1)(B) sets forth a second category of "permissible restrictions," providing that "a State may *exclude* or otherwise restrict coverage of a covered outpatient drug" through any one of four mechanisms: a state may determine that a drug is being prescribed for a use that is not medically accepted by the FDA; a state may enter into a specific agreement directly with the drug's manufacturer to impose specific restrictions on certain drugs; a state may exclude coverage for drugs that are on a list that "may be excluded from coverage or otherwise restricted," such as weight loss, fertility, or hair growth drugs; and finally, since 1993 a state may exclude coverage of a drug if "the State has *excluded coverage* of the drug from its formulary established in accordance with paragraph (4)." *See* 42 U.S.C. § 1396r-8(d)(1)(B) (emphases added).

By asserting that prior authorization has "the same effect" as does exclusion from a formulary, Pet. at 21-22, PhRMA's argument directly contradicts this straightforward statutory framework, and attempts to conflate the imposition of prior authorization restrictions with the exclusion of drugs from coverage. The Medicaid statute clearly recognizes a distinction between subjecting a drug to prior authorization under subsection (d)(1)(A), and excluding that drug from coverage under subsection (d)(1)(B). The rules governing the exclusion of drugs from coverage on a formulary in no way limit the state's ability to impose prior authorization restrictions.

Moreover, the assertion that prior authorization under subsection (d)(1)(A) has "the same effect" as excluding the

drug from coverage under subsection (d)(1)(B)(iv) leads to the obviously untenable result that one or other of these two provisions must be redundant. Since Congress did not enact either provision to serve as a dead letter, the statute itself proves that the two provisions must have distinct meanings. Further proof can be found in the operation of Florida's program: it guarantees coverage of all its non-PDL drugs – all a physician has to do is request authorization, and it will be granted. By contrast, if Florida had chosen to exclude those non-PDL drugs from coverage altogether under subsection (d)(4), the excluded drugs could not be reimbursed by Medicaid absent extraordinary, exigent circumstances. There is a major, substantive difference between imposing a prior authorization restriction and excluding the drug from coverage altogether.

PhRMA responds by pointing to the fact that when a state creates a restrictive formulary under subsection (d)(4), it must still "permit[] coverage of a drug excluded from the formulary . . . pursuant to a prior authorization program that is consistent with paragraph (5)." 42 U.S.C. § 1396r-8(d)(4)(D). In other words, Congress provided that even when a state has excluded a drug from coverage, it must nonetheless satisfy the minimal 24/72 requirements of paragraph (5). So if a physician requests authorization to prescribe a drug that has been excluded from a formulary under subsection (d)(4), the physician is entitled to at least get a 72-hour emergency prescription for his patient "in an *emergency* situation (as defined by the Secretary)." 42 U.S.C. § 1396r-8(d)(5)(B) (emphasis added). But the state need not otherwise grant the request, since it has excluded that drug from Medicaid coverage altogether under subsection (d)(4).

By contrast, AHCA must consider (and indeed does not refuse) *any* request made by a physician for the reimbursement of a non-PDL drug. These drugs have not been excluded from coverage on a restrictive (d)(4) formulary. Rather, they have merely been designated as drugs for which prior authorization must be requested under

(d)(1)(A). As the Eleventh Circuit explained, "the prior authorization requirement of a federal Medicaid formulary, pursuant to subsection (d)(4)(D), is likely to serve a different function than a prior authorization program authorized under subsection (d)(1)(A), (d)(5)." App. 21. Specifically, drugs subjected to prior authorization under subsection (d)(1)(A) are still covered, "provided that the prescribing doctor contacts the state pharmacist." App. 22. Under Florida's program, the "prescribing physicians retain the authority to override any suggestions made by the AHCA state pharmacist." *Id.* n.9. By contrast, "[s]ince a federal formulary *excludes* from coverage Medicaid-eligible outpatient drugs, *see* subsection (d)(1)(B)(iv)," the prior authorization provision specified by subsection (d)(4)(D) merely requires "that a state must *consider* coverage for an excluded drug on a case-by-case basis." App. 21 n.9. Thus, "if the Florida law had actually created a federal formulary, and complied with all the requirements of subsection (d)(4), it would be permissible for the state to retain the final authority over coverage of, or payment for, non-formulary drugs." App. 22 n.9.

PhRMA argues that there is no support for the distinction drawn by the court of appeals between the state's power to subject "any covered outpatient drug" to prior authorization under subsection (d)(1)(A), and its obligation to provide a prior authorization "safety net" to drugs excluded from its formulary, as prescribed by subsection (d)(4)(D). Pet. at 21 n.10. The statute itself does not just support the distinction drawn by the panel – it *requires* that distinction. As explained above, any interpretation that conflates these two provisions, as PhRMA's does, necessarily requires the absurd result that one or other of the provisions be read out of the statute. Moreover, Congress specifically confirmed that the prior authorization safety net for drugs excluded from a (d)(4) formulary should not be equated with the imposition of prior authorization under subsection (d)(1)(A) and (d)(5): the last

sentence of subsection (d)(4) provides quite clearly that "[a] prior authorization program established by a State under paragraph (5) is not a formulary subject to the requirements of this paragraph."[12]

Unsurprisingly, PhRMA has never been able to explain how the plain language of subsection (d)(1)(A) and (d)(5) retains any meaning whatsoever under its interpretation of the law. It has elliptically suggested that there are only limited instances in which it might be permissible for a state to impose prior authorization restrictions without having to satisfy subsection (d)(4)'s requirements for excluding a drug from a formulary – namely, to control a beneficiary's ability to receive more than a certain number of brand-name prescriptions in any given month, or to combat fraud or abuse. Pet. at 22-23. These are undoubtedly legitimate examples of a state's use of prior authorization, but there is no conceivable basis for treating these examples as the entire universe of cases in which a state may impose prior authorization, particularly where the statute provides quite plainly that prior authorization may be imposed on "any covered outpatient drug." Furthermore, these examples are entirely in keeping with Florida's effort in this case to use the prior authorization

[12] For this reason, PhRMA is also incorrect when it asserts that "what PhRMA presented as proof that the Florida program violates SSA § 1927(d)(4)'s formulary requirements, the Eleventh Circuit viewed as proof that the Florida program is not a formulary." Pet. at 12. This profoundly misrepresents the Eleventh Circuit's reasoning: the panel did not reject the notion that Florida's program is a (d)(4) formulary simply because the program fails to satisfy the (d)(4) requirements; rather, the panel recognized that exclusion of a drug from a formulary under subsection (d)(4) constitutes a "restriction" on Medicaid coverage (i.e., exclusion) that is categorically different from Florida's comparatively minor requirement that doctors first contact AHCA before Medicaid pays for non-PDL drugs. App. 19-22; App. 27-28.

power to prevent over-utilization of drugs that are far more costly than their therapeutic equivalents.

B. PhRMA Cannot Demonstrate That The Lower Courts Committed "Plain Error" In Their Interpretation Of Florida Law.

In an effort to show that the Florida Legislature wanted to create a restrictive formulary within the meaning of (d)(4), but simply failed to comply with all of the rules for doing so, PhRMA relies heavily on selective excerpts from the 2001 amendments. For example, PhRMA points out that the 2001 amendments use the word "formulary" on nineteen different occasions, and emphasizes that these amendments created a P&T Committee that satisfies the definition of subsection (d)(4)(A). To the extent that it relies upon the language of the Florida statute, however, PhRMA is obviously making an argument that depends upon the meaning of that state law.[13]

PhRMA implicitly acknowledges that it is asking this Court to review the Eleventh Circuit's interpretation of state law when it notes in passing that this Court "is not bound" by the Eleventh Circuit's interpretation of the 2001 amendments. Pet. at 20 n.9. While this Court may not be "bound," it has repeatedly held that it "rarely reviews a construction of state law agreed upon by the two lower federal courts." *Virginia v. American Booksellers Ass'n*, 484 U.S. 383, 395 (1988). Instead, this Court "ordinarily

[13] As the Eleventh Circuit noted, PhRMA's argument here is somewhat "puzzling," since it asserts simultaneously that the Florida Legislature was "carefully conforming the Florida statutes to the requirements of the governing Medicaid statute," and that Florida nonetheless failed to conform to the requirements set forth in subsection (d)(4)(C). App. 29.

defer[s] to the construction of a state statute given it by the lower federal courts unless such a construction amounts to plain error." *Stenberg v. Carhart*, 530 U.S. 914, 949 (2000) (O'Connor, J., concurring).

Here, both the district court and the Eleventh Circuit rejected PhRMA's argument that the 2001 amendments "created a Medicaid formulary within the meaning of SSA § 1927(d)(4)," Pet. at 20, concluding instead that "a reasonable reading of the Florida law suggests that the state has created a 'prior authorization program' within the meaning of § 1396r-8(d)(1)(A), (d)(5)." App. 19. Both courts were aided in this interpretation by the fact that AHCA's official interpretation is that "the Florida law actually creates a prior authorization program that covers all Medicaid-eligible drugs," an interpretation that AHCA "has consistently advanced . . . since the enactment of the Florida law." App. 21-22. As the Eleventh Circuit recognized, "AHCA's interpretation of the Florida law is entitled to substantial deference," and should not be set aside unless it is "'arbitrary, capricious, an abuse of discretion, or otherwise not supported by law.'" App. 22 (quoting *Enterprise Leasing Co. v. Metropolitan Airports Comm.*, 250 F.3d 1215, 1223 (8th Cir. 2001)). Thus, PhRMA must show that it was "plain error" for the Eleventh Circuit to conclude that AHCA adopted a reasonable interpretation of the 2001 amendments when it implemented those provisions by creating a prior authorization program.

This is a high hurdle indeed, and PhRMA cannot clear it. First, the Eleventh Circuit correctly concluded that the specific terminology used in the 2001 amendments is of little or no guidance in determining whether Florida's PDL is preempted by Federal law. Those amendments use the terms "preferred drug formulary" and "preferred drug list" interchangeably, and neither term is given a definition, either under state law or under the Medicaid statute. App. 28. Thus, "little can be inferred from the choice of words,"

App. 28 (quotation omitted), and there is certainly no basis for concluding that Florida's PDL is preempted based solely on the terminology used in the amendments.[14]

Likewise, the fact that Florida has created a P&T Committee does not mean that this committee *must* have then tried to create a restrictive formulary under subsection (d)(4). The 2001 amendments provide that "[u]pon recommendation of the [P&T Committee], the agency shall adopt a preferred drug list," but nowhere does it suggest that drugs not included on this PDL should be excluded from Medicaid coverage altogether. FLA. STAT. § 409.91195(4). Rather, the amendments provide that non-PDL drugs shall be available under Medicaid, subject only to prior authorization. FLA. STAT. § 409.91195(5). Finally, the 2001 amendments also plainly provide that the P&T Committee may "make recommendations to the agency regarding the prior authorization of any prescribed drug covered by Medicaid." FLA. STAT. § 409.91195(10).

There is therefore no reason to believe that the intention of the 2001 amendments was for the P&T Committee to create a restrictive Medicaid formulary. The most that can be said about the language of these amendments is that they would *permit* AHCA to work with the P&T Committee to create a restrictive formulary. App. 29. But they in no way require AHCA to do so, and AHCA plainly

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[14] PhRMA grossly misrepresents the record by stating that "AHCA insisted that the 2001 amendments created a Medicaid 'preferred drug formulary with prior authorization' subject to SSA § 1927(d)(4)." Pet. at 10. AHCA has consistently maintained that the 2001 amendments do *not* create a restrictive formulary within the meaning of subsection (d)(4). App. 13-14 n.5. And contrary to PhRMA's misrepresentations, Pet. at 10-11, when CMS questioned AHCA's terminology, AHCA immediately responded with a letter that made abundantly clear its view that it was *not* creating a (d)(4) formulary. App. 13-14 (excerpting portions of AHCA letter).

has not attempted to do so. To the contrary, AHCA has consistently interpreted these amendments to mean that non-PDL drugs continue to be covered under Medicaid, and that prior authorization must be granted for any such drug. App. 14. As the Eleventh Circuit noted, AHCA has maintained this interpretation of the amendments right from the start, before the amendments were finalized and before PhRMA launched this litigation. *Id.* at n.5.

In short, PhRMA cannot show "plain error." It was perfectly reasonable for AHCA to implement the 2001 amendments by creating a prior authorization program, and obviously correct for the Eleventh Circuit to uphold that interpretation.

IV. This Court Should Not Hold The Petition Pending Disposition Of *Concannon*.

PhRMA argues that this Court's decision in *Concannon* "could affect an underpinning of the Eleventh Circuit's decision, such that an order granting certiorari and vacating the judgment below may be warranted." Pet. at 26. While it insists that the issues presented in this case and *Concannon* are "distinct," it also maintains that they "share a common feature" – namely, "both read the prior authorization provisions in SSA § 1927(d)(1) and (5) to allow a state to use prior authorization for any purpose whatsoever, free of the strictures that the other provisions of the federal statute impose." *Id.*

But PhRMA invokes very different Medicaid "strictures" in *Concannon* than the one it invokes in this case. Here, it invokes only the formulary provision – subsection (d)(4). There, all three of the statutory arguments advanced by PhRMA focus on the fact that Maine has used prior authorization to negotiate rebates for *non*-Medicaid beneficiaries. *See* Brief of Petitioner (PhRMA) at 17-18, *PhRMA v. Concannon*, No. 01-188 (U.S. filed July 31, 2001) (prior authorization "solely in order to further

Maine's interest in raising funds for non-Medicaid state residents" violates 42 U.S.C. § 1396a(a)(19)); 18-19 (arguing that Maine's program is a "diversion of the Medicaid program to serve non-Medicaid purposes"); 19-20 (arguing that "no Medicaid purpose is served" by Maine's program because it benefits non-Medicaid residents).

None of these arguments has any application to this case. Florida's PDL is used solely to negotiate supplemental rebates for Medicaid beneficiaries, and is not used to negotiate rebates for any non-Medicaid residents. Thus, the arguments advanced by PhRMA in *Concannon* are inapposite to this case. It therefore cannot be the case that this Court's resolution of *Concannon* could even possibly "affect an underpinning of the Eleventh Circuit's decision." Pet. at 26. Likewise, it is simply not correct to say, as PhRMA does, that the Eleventh Circuit "rel[ied] heavily" on *Concannon*. Pet. at 12. It is self-evident from the Eleventh Circuit's opinion and from PhRMA's Petition that the Eleventh Circuit did *not* rely on *Concannon* at all, but instead relied solely upon its own interpretation of the Medicaid statute. App. 19-29.

PhRMA vaguely claims that there might be "direct implications for this case" if this Court decides that the prior authorization provisions "must be construed *in pari materia* with the other provisions of the Medicaid statute," but that is like saying there might be "direct implications" for this case if this Court decides to use normal legal reasoning in *Concannon*. Obviously, the provisions of the Medicaid statute must be construed *in pari materia*. But as PhRMA acknowledges, this case and *Concannon* implicate substantively "distinct" provisions of the Medicaid statute. No matter how this Court construes the provisions at issue in *Concannon*, those provisions were not raised by PhRMA in this case, and do not have any application to this case because Florida, unlike Maine, has not used its prior authorization power to negotiate rebates for the benefit of non-Medicaid patients.

CONCLUSION

For the forgoing reasons, the Petition for Writ of Certiorari should be denied.

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